

REMARKS

The previous Office Action restricted claims 1-28 under 35 U.S.C. § 121 as follows:

- I. Claims 1-4, 10, 11, 20-26 are said to be drawn to a device for boring into bone, classified in class 606, subclass 80; and
- II. Claims 5-9 are said to a method of attaching a suture to a bone, classified in class 606, subclass 148; and
- III. Claims 12-14 are said to be drawn to detachable tip for a needle, classified in class 606, subclass 223.

Applicant traversed the restriction and the Examiner agreed to consider claims 15-19 and 27-28, but made the restriction relative to claims 5-9 and 12-14 final. Applicant thanks the Examiner for consideration of the additional claims. Also, applicant reserves its rights relative to the restriction requirement including the right to argue for additional term for any patents issuing on this and any future applications.

Although not explicitly stated, it is assumed that claims 5-9 and 12-14 were withdrawn from further consideration. Applicants herein cancel these claims without prejudice to applicant's right to seek claims of such scope in a continuation or divisional application.

Several informalities in the specification were detected during preparation of this amendment. The typos are corrected herein. The drawings are also corrected herein.

The Office Action rejected claims 1-4, 10, 11, and 15-22 under 35 U.S.C. Section 102 (b) as being anticipated by Romano, U.S. Pat. No. 5,509,918. Claims 23 and 28 were rejected under 35 U.S.C. Section 103 (a) as being unpatentable over Bonutti, U.S. Pat. No. 5,269,785. Claims 24-27 were rejected under 35 U.S.C. Section 103 (a) as being unpatentable over Bonutti in view of Romano.

Independent claims 1, 10, 11, 15, 20 and 23 are currently pending.

With respect to claim 1, Romano does not disclose a needle adapted for boring into bone. The Office Action identified elements 234 and 240 as a needle. We respectfully disagree that these elements constitute a needle in the context of claim 1. Romano discloses a curved guide arm 234 and a cutting bit 240. Romano uses a drill comprised of a flexible cable that rotates a drill bit. Romano uses a drive mechanism to provide a rotational force to rotate a

cutting bit to produce a curved bore. The rounded end cutting bit removes portions of the bone to create the bore.

In contrast, claim 1 sets forth a needle adapted for boring into bone. Boring a needle through bone is a cleaner process than drilling. A drill bit grinds into bone, ripping away pieces of bone as it rotates. Advancement of Applicant's needle has the potential to cause less trauma to the bone than the drill bit of Romano. Additionally, a needle is a much less complex component than the drilling assembly of Romano. Thus, the rejection of claims 1-4 based on Romano should be withdrawn.

With respect to claim 10, the Office Action took the position that elements 100, 102, 182 and 244 of Romano constitute a needle retractor. We respectfully disagree. Romano discloses a push rod 100, a push rod 102, push bar 182 and push line 244. None of these elements constitute a needle retractor, nor do they meet the limitations of claim 10. For example, claim 10 sets forth "a needle retractor, which retracts said needle when a force on said handle in a particular direction is lower than a predetermined amount, prior to said base retreating from said bone in response to a lowering of the force." This limitation is not disclosed in Romano. The Office Action references columns 6-9, lines 1-67. Applicants have reviewed these passages and do not find this limitation therein. Thus, the rejection of claim 10 should be withdrawn.

With respect to claim 11, the Office Action took the position that elements 100, 102, 182 and 244 of Romano constituted a needle advancer and that the disclosure in columns 6-9, lines 1-67 anticipates claim 11. We respectfully disagree. Romano discloses a push rod 100, a push rod 102, push bar 182 and push line 244. None of these elements meet the limitations of claim 11, either alone or in combination. For example, claim 11 sets forth "and a needle advancer, which advances said needle only when a force on said handle in a particular direction is higher than a predetermined amount, said predetermined force assuring that said base is urged against said bone." This limitation is not disclosed or suggested in Romano. The Office Action references columns 6-9, lines 1-67. Applicants have reviewed these passages of Romano and does not find this limitation therein. Thus, the rejection of claim 11 should be withdrawn.

Claim 15 is amended herein to correct a typographical error. The Office Action took the position that elements 242 and 246 of Romano were "hinges" in the context of claim 15.

Romano does disclose pivot pins 242 and 246. However, neither of these elements comprise a hinge in the context of claim 15. Claim 15 sets forth:

A self-aligning device for boring into bone, comprising:
a boring head having at least two boring tips;
a body;
a handle attached to said body; and
a hinge coupling said head to said body at a location substantially equidistant from said boring tips.

The invention set forth in claim 15 promotes uses where a substantially equal force is applied to the boring tips. Romano teaches the *opposite*. In Romano, to avoid interference between the linkage and damage to the two cutting bits 240 that would occur if they contacted each other, left clip 104 is retracted from its maximum displaced position (Fig. 2B), before right clip 116 is advanced to a point of maximum displacement (Fig. 2C). See column 7, lines 48-53. Thus, the rejection of claim 15 based on Romano should be withdrawn.

Claims 20 is a method claim. The Office Action stated that the method steps would “inherently” be carried out in the operation of the device. Applicants respectfully disagree.

A limitation is inherent if it is the natural result flowing from the explicit disclosure of Romano. *Eli Lilly v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001). The Office Action does not explain how the method steps are the natural result of the explicit disclosure of Romano. Applicants submit that Romano does not disclose the method steps of amended claim 20. Romano teaches boring a hole with a first, bone boring device and using a second, curved surgical needle with a stitch to embed the stitch in the hole bored by the first device. See column 1, lines 20-22. Thus, the rejection of claim 20 should be withdrawn.

With respect to claim 23, Applicants agree that Bonutti does not anticipate claim 23. However, the Office Action stated, “. . . applicant is not positively claiming the needle” We respectfully disagree.

Claim 23 sets forth:

Apparatus for forming a channel in a bone, comprising:
at least one drill bit for drilling into a bone and detecting a channel formed therethrough and an aperture from the outside of said bit to said channel; and
at least one needle adapted to fit through said aperture. [Italics supplied.]

Clearly, "at least one needle" is positively recited in claim 23. Thus, since Bonutti does not anticipate the claim, and since the needle is claimed, this rejection should be withdrawn.

The dependent claims are allowable for the reasons set forth above with respect to their respective independent claims.

Examination and reconsideration of the application as amended is requested.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

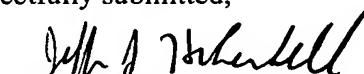
In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested. Allowance of the pending claims at an early date is solicited.

A supplemental information disclosure statement, a request for a one-month extension of time, and a transmittal sheet accompany this amendment. Please charge to Deposit Account No 501921 the fees for the timely submission of these documents.

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Respectfully submitted,

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